CENTER FOR HEALTH INFORMATION & ANALYSIS DATA USE AGREEMENT FOR USE WITH REQUESTS FOR DE-IDENTIFIED DATA

This Data Use Agreem	ent ("Agreement") is entered into be	etween the Center for Health Information and
Analysis ("CHIA") and		("Data Recipient"), effective as of the
	[NAME OF ORGANIZATION]	

date of execution below. The undersigned Data Recipient and all its authorized representatives, subcontractors, agents, and employees, in consideration for the receipt of De-identified Data, as defined in 957 CMR 5.02, from the All-Payer Claims Database and/or Hospital Discharge Database, or any data subsets derived therefrom ("De-identified CHIA Data"), agree that they will observe all of the conditions set forth below regarding the use of De-identified CHIA Data.

Data Recipient Obligations

- 1) The Data Recipient, its employees, agents, and/or contractors shall use De-identified CHIA Data ONLY for the specific purpose(s) stated in the Application submitted to CHIA pursuant to 957 CMR 5.00 and as approved (with or without additional restrictions) by the Executive Director, and in accordance with the terms of this Agreement. The approved application, including any additional restrictions imposed by the Executive Director, is attached hereto as Exhibit A.
- 2) The Data Recipient, its employees, agents, and/ or contractors shall follow all policies and procedures set forth in its Application, and shall use De-identified CHIA Data in conformity with each of the assurances made in the Application attached as Exhibit A.
- 3) The Data Recipient shall limit access to the De-identified CHIA Data to such authorized employees, agents, or contractors as are reasonably necessary to undertake the project approved by the Executive Director as described in Exhibit A.
- 4) All Data Recipient employees, agents, and contractors provided with access to De-identified CHIA Data will sign the Confidentiality Agreement attached hereto as Exhibit B.
- 5) The Data Recipient shall provide CHIA with the names, contact information, and copies of the Confidentiality Agreements executed by any Data Recipient employees, agents, or contractors given access to De-identified CHIA Data.
- 6) The Data Recipient shall ensure that all employees, agents, and contractors with access to the data comply with the terms of this Agreement, as well as any applicable state and federal data privacy and security laws or regulations. De-identified CHIA Data may not be used for any purposes contrary to local, state, and federal laws and regulations. Compliance with all local, state, and federal laws and regulations is the sole responsibility of the Data Recipient.

- 7) The Data Recipient shall not publish or otherwise disclose in any public paper, report, website, statistical tabulation, or similar document any data on ten or fewer individuals or data derived from ten or fewer claims.
- 8) The Data Recipient agrees and acknowledges that because CHIA Data relies, in part, on the existence and proper operation of equipment and software that is outside of the control of CHIA, and relies on information controlled by and supplied by third parties, CHIA makes no representations, warranties, or guarantees as to the accuracy or completeness of any data.
- 9) The Data Recipient shall maintain or cause to be maintained sufficient insurance coverage as shall be necessary to insure Data Recipient and its employees, agents, and subcontractors against any and all claims or claims for damages arising under this Agreement.
- 10) The Data Recipient agrees to defend, indemnify, and hold harmless CHIA from and against any and all claims, damages, losses, and liability, including reasonable attorney's fees, costs, expenses, fines, and penalties sustained or incurred by CHIA relating to or resulting from any action, failure, negligence, or willful acts or omissions of the Data Recipient's officers, employees, agents, third party contractors, or representatives, including failure to comply with any local, state, and/or federal laws and/or regulations. The Data Recipient agrees not to hold CHIA liable to the Data Recipient, or any other party entitled to indemnification, for any consequential, indirect, special, exemplary, or punitive damages arising under or in connection with this Agreement or the use of CHIA Data. This includes any loss of profits, loss of revenue, loss of equipment use, or loss of data or information of any kind, even if such party has been advised of the possibility of such damages.
- 11) The applicant will cite the Center for Health Information and Analysis as the source of the data in any studies, reports, or products in which De-Identified CHIA data are used.

Data Recipient's Confidentiality and Security Obligations

- The Data Recipient shall maintain such policies, procedures, and systems as may be reasonably necessary to prevent unauthorized parties from having access to, using, disclosing, processing, copying, modifying, corrupting, rendering unavailable, destroying, introducing computer code into, or otherwise performing activities or operations harmful to the privacy, availability, accessibility, integrity, structure, format, or content of any De-identified CHIA Data that may be transmitted to or accessed by the Data Recipient.
- 2) The Data Recipient shall implement the security measures described in "Safeguarding Deidentified CHIA Data," attached hereto as Exhibit C.
- 3) The Data Recipient agrees to return or destroy any De-identified CHIA Data provided pursuant to this Data Use Agreement and to provide CHIA with an executed copy of Exhibit D, attesting to any such data destruction.
- 4) The Data Recipient agrees that it will permit CHIA, at its discretion, to audit the Data Recipient's compliance with this Data Use Agreement by providing CHIA with reasonable access to documentation related to the access, use, and disclosure of De-identified CHIA Data.

- 5) CHIA's exercise or non-exercise of any authority under this Data Use Agreement to inspect the privacy or security practices of the Data Recipient shall not relieve the Data Recipient of any obligations set forth herein, nor be construed as a waiver of any of the Data Recipient's obligations or as an acceptance of any unsatisfactory practices or privacy or security failures or breaches by the Data Recipient.
- 6) The Data Recipient agrees that if it fails to comply with any of the requirements of this Data Use Agreement, or any applicable state or federal regulation or law, CHIA may deny future access to any CHIA Data, terminate current access to CHIA Data; and/or demand immediate return or destruction of all CHIA Data.

Terms and Termination

- 1. The effective date of this Agreement shall be the date of execution below.
- 2. This Agreement shall be in effect until Data Recipient attests to the return or destruction of the CHIA Data provided pursuant to this Agreement.

Warranties; Limitations of Liability

CHIA MAKES NO REPRESENTATIONS OR WARRANTIES TO ANY PERSON OR ENTITY WITH RESPECT TO CHIA DATA, THE SOFTWARE, OR ANY OTHER INFORMATION PROVIDED BY CHIA OR ITS AGENTS WITH RESPECT TO ANY OF THE FOREGOING, AND HEREBY DISCLAIMS ALL IMPLIED WARRANTIES WITH RESPECT TO CHIA DATA, INCLUDING WARRANTIES OF MERCHANTABILITY AND FITNESS FOR A PARTICULAR PURPOSE. FURTHER CHIA MAKES NO WARRANTY, GUARANTEE OR REPRESENTATION REGARDING THE USE, OR ANY INTENDED, EXPECTED, OR ACTUAL RESULTS OF THE USE, OF CHIA DATA, THE SOFTWARE, OR ANY OTHER INFORMATION PROVIDED BY CHIA IN TERMS OF CORRECTNESS, ACCURACY, RELIABILITY, OR OTHERWISE. CHIA DOES NOT MAKE ANY WARRANTIES THAT CHIA DATA, SOFTWARE, OR ANY OTHER INFORMATION PROVIDED BY CHIA WILL BE ERROR-FREE. CHIA SPECIFICALLY DISCLAIMS ALL EXPRESS WARRANTIES NOT STATED HEREIN AND ALL IMPLIED WARRANTIES, INCLUDING THE IMPLIED WARRANTIES OF MERCHANTABILITY AND FITNESS FOR A PARTICULAR PURPOSE. NO CHIA AGENT OR EMPLOYEE IS AUTHORIZED TO MAKE ANY EXPANSION, MODIFICATION, OR ADDITION TO THE LIMITATION AND EXCLUSION OF WARRANTIES IN THIS AGREEMENT.

CHIA USES AVAILABLE TECHNOLOGY TO MATCH PATIENT IDENTITIES WITH THEIR HEALTH INFORMATION IN ORDER TO PROVIDE PARTICIPANTS WITH DE-IDENTIFIED PATIENT INFORMATION. BECAUSE PATIENT INFORMATION IS MAINTAINED IN MULTIPLE PLACES, NOT ALL OF WHICH ARE ACCESSIBLE TO CHIA, AND BECAUSE NOT ALL PATIENT INFORMATION IS KEPT IN A STANDARD FASHION OR IS REGULARLY UPDATED, IT IS POSSIBLE THAT FALSE MATCHES MAY OCCUR OR THAT THERE MAY BE ERRORS OR OMISSIONS IN THE INFORMATION. CHIA DOES NOT AND CANNOT INDEPENDENTLY VERIFY OR REVIEW THE INFORMATION TRANSMITTED FOR ACCURACY OR COMPLETENESS.

Miscellaneous

1. Amendment of Agreement.

- i. A modification by a Party to this Agreement of its policies, procedures, processes, and/or systems used in connection with its obligations under this Agreement shall not be deemed a breach of or an amendment to this Agreement, unless (i) such modification unreasonably interferes with another Party's ability to fulfill its obligations under this Agreement, or (ii) such modification is contrary to or interferes with a specific obligation stated in the Application.
- ii. Any Party may seek to amend this Agreement in order to accommodate any new legislation, regulation, case holding, or legal order issued or proposed to be issued by a federal or state agency of competent jurisdiction, which, in the reasonable judgment of the party, (a) invalidates or is materially inconsistent with this Agreement; (b) would cause a Party to be in violation of the law by its continued performance under this Agreement; (c) would jeopardize the tax-exempt status of the Party (if applicable) by its continued performance under this Agreement; or (d) would jeopardize the licensure, accreditation or participation in good standing in a federal health benefit plan of the Party by its continued performance under this Agreement. A Party wishing to seek such an amendment shall notify the other Parties in writing, including any proposed terms of amendment, no later than ninety (90) days prior to the proposed effective date of the amendment. The Parties shall then negotiate in good faith to agree upon an amendment. In the event no agreement is reached, no amendment shall be effective, and the Party seeking amendment may elect to terminate the Agreement by written notice.
- Entire Agreement. This Agreement, including the Application and any attachments to the Application, incorporating this Agreement by reference, and as amended from time to time, constitutes the entire agreement and understanding between the Parties and supersedes all prior oral or written agreements and understandings between them with respect to such services.
- 3. <u>Assignment</u>. No Party may assign or transfer any or all of its rights and/or obligations under this Agreement or any part of it, nor any benefit or interest in or under it, to any Third Party without the prior written consent of all other Parties.
- 4. <u>Notices</u>. Any notice that may be, or is required to be, given under this Agreement shall be written and shall be sent by first class mail, fax, courier, or as an Electronic Record attached to an e-mail. All notices shall be effective upon receipt at the addresses stated in the signature lines below.
- 5. <u>Intent to Comply with Laws</u>. This Agreement shall be interpreted consistently with all applicable information privacy and protection laws, and shall be construed and interpreted liberally in favor of the protection of protected health information and confidential information. In the event of a conflict between applicable laws, the more stringent law shall be applied.
- 6. <u>Applicable Law for Judicial Proceedings</u>. The laws of the Commonwealth of Massachusetts shall apply to all judicial proceedings arising out of this Agreement.
- 7. Mutual Representations.

- i. Each party to this Agreement represents to the other Party that, at all times during the Term and at such other times as may be indicated, it shall comply with, and as applicable, shall require its directors, officers, and employees to comply with, its duties and obligations pursuant to this Agreement, including but not limited to duties and obligations that survive the termination of this Agreement.
- 8. <u>Enforceability</u>. If any provision of this Agreement is held invalid or unenforceable for any reason but would be valid and enforceable if appropriately modified, then such provision will apply with the modification necessary to make it valid and enforceable. If such provision cannot be so modified, the Parties agree that such invalidity will not affect the validity of the remaining provisions of the Agreement.
- 9. <u>Force Majeure</u>. Neither Party will be liable for nonperformance or delays caused by acts of God, wars, riots, strikes, fires, floods, earthquakes, government restrictions, terrorist acts, or other causes beyond its reasonable control.
- 10. <u>Use of Electronic Signatures and Electronic Records</u>. The Parties may elect to establish processes for the use of Electronic Records in the management of and compliance with this Agreement. Such document may include published policies, procedural information, notices, and any other document arising from or pertaining to this Agreement, including this Agreement itself. Any such process must include the establishment of a mutually acceptable Electronic Signature process, which complies with federal and state laws.

A Data Recipient who violates this Data Use Agreement, or 957 CMR 5.00, will be subject to all penalties and remedies allowed by law, including but not limited to M.G.L. c. 214 § 1B and M.G.L. c. 93A. CHIA will notify state and federal law enforcement officials, as applicable, of any violations of 957 CMR 5.00 and of any data breaches in connection with any violation of this agreement.

It is the sole responsibility of the Data Recipient to ensure compliance with all other local, state, and federal laws and regulations.

Signed:

	BY:		
Name of Data Recipient Organization		Authorized Signature	
		Name	
		Title	
		 Date	

Exhibit A – Data Use Agreement

[Insert Approved Application for Data Submitted Pursuant to 957 CMR 5.00]

Exhibit B – Data Use Agreement

CENTER FOR HEALTH INFORMATION AND ANALYSIS CONFIDENTIALITY AGREEMENT FOR USE WITH REQUESTS FOR DE-IDENTIFIED DATA

l,	, hereby acknowledge that, in	n connection with a
•	ne All-Payer Claims Database data and/or H Agreement") with CHIA, I may acquire or h	
I will comply with all of the terms of the of the comply with all of the terms of the fand of the terms of the complex of the	he Agreement with CHIA regarding the acc	ess, use, and disclosure
I will not, either directly or indirectly, any unauthorized person at any time.	disclose or otherwise make confidential in	formation available to
· · · · · · · · · · · · · · · · · · ·	idual patient whose information is include in to me, my family members, neighbors, l else.	
confidentiality and data security may	s Agreement and/or laws or regulations problems of subject me to criminal or civil liability. I further enforcement officials, as applicable, of any agreement.	rther understand that
Signed:		
Signature	- Date	
Print Name:		
Title:		-
Organization:		-
Address:		-
Telephone:	E-Mail:	

Exhibit C - Data Use Agreement

SAFEGUARDING DE-IDENTIFIED CHIA DATA

I. Purpose

This document establishes confidentiality and security requirements for Data Recipients receiving only De-identified CHIA Data.

II. Definitions

For the purpose of this document, the term:

"Data Recipient" shall include any entity receiving CHIA Data pursuant to 957 CMR 5.04, 957 CMR 5.05, and/or 957 CMR 5.06.

"Employee" shall include all employees, contract employees, individual consultants, volunteers, trainees, student interns, members, directors, officers, partners, agents, and subcontractors who may have access to CHIA Data.

"CHIA Data" shall include any data received from CHIA pursuant to an approved request or application under 957 CMR 5.00.

"De-identified Data" means data that does not identify an individual patient and with respect to which there is no reasonable basis to believe the data can be used to identify an individual patient. CHIA shall de-identify data using the standards and methods required by the Health Insurance Portability and Accountability Act of 1996, 42 U.S.C. § 1320d-1320d-8, and its implementing regulations, including 45 CFR Parts 160, 162 and 164, as amended from time to time. Level I data in CHIA's APCD and Acute Hospital Case Mix Databases include only De-identified Data.

"Media" shall include all forms of physical storage such as Compact Disks (CDs), DVDs, tapes, drives, and other storages devices.

III. General Requirements

The Data Recipient agrees that it will not use or further disclose De-identified CHIA Data other than as permitted or required by the Agreement.

The Data Recipient will take all reasonable precautions to ensure the physical security of the Deidentified CHIA Data under its control and to prevent the unauthorized use or disclosure of such data.

The Data Recipient will take all reasonable precautions to ensure that access to the data is limited to authorized Employees who have executed the Confidentiality Agreement attached as Exhibit B to the Data Use Agreement with CHIA.

The Data Recipient agrees to report to CHIA any unauthorized use or disclosure of De-identified CHIA Data of which it becomes aware within three (3) days of becoming aware of such unauthorized use or disclosure.

The Data Recipient may maintain the De-identified CHIA Data on its system only for as long as required for the project approved by CHIA.

When a Data Use Agreement expires or is terminated, all CHIA Data, files, and media in possession of the Data Recipient are to be destroyed or returned to CHIA. The Data Recipient must sign an affidavit, attached hereto as Exhibit D, confirming that all CHIA Data, files, and media have been returned to CHIA.

The Data Recipient agrees to comply with all state and federal laws applicable to De-identified CHIA Data during the term of the Agreement.

IV. Vendors

The Data Recipient is not allowed to transfer CHIA Data to any third party, including contractors, vendors, or agents, without CHIA's written approval. All approved data transfers are subject to the same, or additional, conditions, as defined in the Data Use Agreement.

The Data Recipient shall provide CHIA with the names and contact information of all contractors, vendors, and agents who will be provided with access to CHIA Data. Prior to receiving access to CHIA Data, contractors, vendors, and agents must execute the Confidentiality Agreement attached to the Data Use Agreement as Exhibit B.

Exhibit D - Data Use Agreement

CERTIFICATION OF PROJECT COMPLETION & DESTRUCTION OR RETENTION OF DATA

NOTE: Data must be destroyed so that it cannot be recovered from the electronic storage media. Acceptable methods include the use of file wiping software implementing at a minimum DoD.5200.28-STD (7) disk wiping, and the degaussing of backup tapes. Electronic storage media such as floppy disks, CDs, and DVDs used to store data must be made unusable by physical destruction. All data destruction must comply with the requirements of M.G.L. c. 93I.

must comply with the requirements of M.G.L. c. 93I.
The undersigned hereby certifies that the project described in this Application is complete as of this date:
The undersigned further certifies as follows (check the appropriate section):
☐ I/we certify that we have destroyed all data received from CHIA in connection with this project, in all media that was used during the project. This includes, but is not limited to, data maintained on hard drives and other storage media.
☐ I/we certify that we are retaining the data received in connection with the aforementioned project pursuant to the following health or research justification (please include an attachment providing detail and state how long the data will be retained).
☐ I/we certify that we are retaining the data received from CHIA in connection with the aforementioned project as required by the following law: [Reference the appropriate law and indicate the timeframe]
SIGNATURES:
Applicant:
Date:
For the Applicant's Organization: